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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,718	07/05/2001	Stefanie Sprunck	514413-3886	4044

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.	Applicant(s)	
	09/899,718	SPRUNCK ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

This Non-Final Office Action is a Response to the "Amendment and Response to Office Action" filed 26 March 2003 (Paper No. 12) in reply to the Non-Final Office Action mailed 28 August 2002 (Paper No. 10). Claims 1-16 were considered in Paper No. 10. Claims 1-16 were amended and claims 17 and 18 were added in Paper No. 12. Claims 1-18 are pending and under consideration.

Priority

Receipt of a certified copy of German application 10032379.0 is acknowledged. All certified copies of the priority documents have now been received.

Response to Amendment

Claim Objections

Objection to claims 6, 11 and 12 is withdrawn.

Claim Rejections - 35 USC § 101

Rejection of claims 1-3, 13 and 14 under 35 U.S.C. § 101 is withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-16 stand rejected, and claim 17 is rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the claimed subject matter for reasons of record in Paper No. 10 and herein below in the "Response to Arguments".

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Claims 14 and 16 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for reasons of record in Paper No. 10 and herein below in the "Response to Arguments".

Rejection of claims 1-16 under 35 U.S.C. § 112, second paragraph, as indefinite is withdrawn.

Claim Rejections - 35 USC § 102

Rejection of claims 1-12 and 15 as anticipated by Visser et al. (1991) *Plant Mol. Biol.* 17:691-699 and claims 1-8 and 11 as anticipated by Steege et al. (1992) *Plant Mol. Biol.* 20: 19-30 is withdrawn in view of the amendments and arguments of record in Paper No. 12.

Response to Arguments

Claim Rejections - 35 USC § 112, possession

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for the broad class of *any* and *all* DNAs with caryopsis-specific promoter activity and having the indicated similarity to the disclosed sequence.

In response to the rejection, Applicant has amended claim 1 such that part d) is limited to sequences that hybridize under stringent conditions, which are set forth in the specification as conditions that are considered in the art to constitute high stringency. Therefore, the sequences encompassed by part d) of claim 1 are adequately described.

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However, the amended claim 1, part e), still encompasses nucleic acid sequences having as little as 75% identity with the disclosed nucleic acid sequence. Applicant submits that the DNA of the invention is structurally and functionally defined. However, the Guidelines for Written Description state "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus", "In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Federal Register, Vol. 66, No. 4, Column 2, page 71436). Although applicant has limited the structures encompassed by the claimed genus, a genus of nucleic acids having 75% identity embraces widely variant species which cannot be described by disclosing only one species within the genus, as in the instant case. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics (see MPEP 2163 (ii)). However, the instant disclosure does not set forth the relevant identifying characteristics of a nucleic acid sequence having the function of a caryopsis-specific promoter such that the skilled artisan would recognize that Applicant was in possession of all nucleic acids having that function and at least 75% identity with the sequence defined by SEQ ID NO:1.

For these reasons and reasons of record in Paper No. 10, new claim 17, also lacks adequate written description for the claimed genus of nucleic acid molecules.

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Claim Rejections - 35 USC § 112, enablement

Claims 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for a method of suppressing any gene in the caryopsis of a plant. In response to the rejection, Applicant argues that the disclosure demonstrates that the promoter of the invention can provide tissue-specific expression and can be used to express nucleic acids that are functionally linked to the promoter sequence. Applicant argues that the promoter can be used to express an antisense-RNA or ribozyme. Applicant argues that, because the promoter is specifically active in the caryopsis of plants, it is clear that it can be used for caryopsis-specific expression of ribozymes or anti-sense RNA. Applicant further argues that preparation and design of anti-sense sequences and ribozymes are standard methods routinely used by the skilled artisan and cites two examples (i.e., Tada *et al.* and Zhang *et al.*) wherein the expression of individual genes was suppressed via antisense technology. Applicant cites *In re wands*, 8 USPQ 2D 1400 (Fed. Cir. 1988) emphasizing the court's statement that "a considerable amount of experimentation is permissible, if it is routine". Applicant argues that the prior art is replete with examples of anti-sense RNA and ribozyme inhibition, and the relative level of skill in the art is high. Applicant states, "as with any promoter, the use of the promoter of the present invention in anti-sense RNA or ribozyme inhibition involves a certain amount of experimentation. However, there is no indication that more than routine experimentation is required to optimize the ribozyme or antisense sequence to be fused to the promoter to obtain suppression of the target gene in the caryopsis" (page 8).

These arguments have been fully considered but are not found persuasive because they fail to account for the scope of the claimed subject matter. The claims are directed to a method of

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caryopsis-specific suppression of any gene. Thus, the enabling disclosure must provide adequate guidance such that the skilled artisan could suppress expression of any and all genes in the caryopsis without engaging in undue experimentation. According to the court in *In re Wands*, “[t]he determination of what constitutes undue experimentation in a given case requires the application of standard reasonableness, having due regard for the nature of the invention and the state of the art” (at 1404). The instant disclosure provides a method of expressing an anti-sense or ribozyme construct in the caryopsis. The art provides some anti-sense and ribozyme molecules that are effective inhibitors. However, the art cited in the previous office action teaches that for any given target molecule, an effective antisense molecule must be identified by trial and error experimentation. Therefore, to practice the claimed invention commensurate with its full scope, the skilled artisan would have to engage in trial and error experimentation to identify an effective inhibitory antisense or ribozyme molecule for each and every gene expressed in the caryopsis. Clearly this degree of experimentation, even if it could be accomplished using techniques that are routine in the art, would be considered undue according to the application of standard reasonableness. Therefore, the skilled artisan could not practice the claimed invention commensurate with its full scope without engaging in undue experimentation.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in limiting the isolated nucleic acid molecule of claim 1 to a promoter that is active in plants. As the nucleic acid molecule of claim 1 is already limited to a promoter that is active in the caryopsis, it is unclear how claim 2 further limits the nucleic acid molecule of claim 1.

Claim 13 is indefinite because it fails to set forth a terminal process step that clearly relates back to the preamble. Amending the claim to read, for example, "...wherein the nucleic acid molecule drives expression of genes under the control of the nucleic acid molecule in caryopsis" would be remedial.

Claim 14 is indefinite as it is now amended to read, "wherein the nucleic acid molecule suppressed expression of genes under the control of the nucleic acid molecule". Because the nucleic acid molecule of claim 1 is a promoter, the claim reads as though the promoter suppresses expression of the genes to which it is operably linked. Based on the specification, which describes antisense and ribozyme molecules it would seem that applicant intends to claim a method wherein the nucleic acid molecule under the control of the promoter suppresses expression of endogenous genes. Amending the claim accordingly would be remedial.

Allowable Subject Matter

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Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
April 10, 2003



**JAMES KETTER
PRIMARY EXAMINER**